a4

10. (Amended) The connector defined in claim 2 wherein the ring ~~is~~ produced from a tube by removing interdigitated portions from the tube, alternating removed portions extending in from opposite ends of the tube.

REMARKS

I. Introduction

Claims 1-24 were pending in the above-identified patent application. Applicants have amended the specification to update the status of two referenced patent applications. Claims 2 and 10 have been amended to correct typographical errors.

The Examiner rejected claims 1-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,036,702.

The Examiner rejected claims 1-5 and 24 under 35 U.S.C. § 102(b) as being anticipated by Lazarus et al. European Patent No. 0680734 (hereinafter "Lazarus"). Claims 1-4, 6, 16, and 24 were rejected under 35 U.S.C. § 102(b) as being anticipated by Dwyer et al. European Patent No. 0701800 (hereinafter "Dwyer"). Claims 1-24 were rejected under 35 U.S.C. § 102(e) as being anticipated by Goldsteen et al. U.S. Patent No. 5,976,178 (hereinafter "Goldsteen"). Claims 8 and 9 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lazarus or Dwyer in view of Weier.

The Examiner objected to claim 2 and the specification because of informalities.

The Examiner's rejections are respectfully traversed.

II. Objection to the Specification

The Examiner objected to the specification because the continuing data is not updated with the current status of the parent case, and the patent number for Goldsteen et al. application No. 08/745,618 (hereinafter "Goldsteen") can now be entered.

Applicants have amended the specification to update the status of the parent case and Goldsteen. Therefore, applicants respectfully request the Examiner to withdraw his objections to the specification.

III. Objection to Claim 2

The Examiner objected to claim 2 because of an informality. The Examiner asserts that claim 2 adds further limitations to an element previously cited and modified, and therefore "comprises" should be replaced with --further comprises--. Applicants have amended claim 2 by replacing "annular structure" with --first substructure--, which is an element that was not previously modified, to correct a typographical error. Therefore, applicants submit that this amendment is not a "substantial amendment related to

patentability" within the meaning of Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F. 3d 558, 56 USPQ 2d 1865 (Fed. Cir. 2000), but instead relates merely to a matter of form.

Accordingly, the objection to claim 2 should be withdrawn.

IV. Amendment to Claim 10

Applicants have amended claim 10 to correct a typographical error. The intention of applicant's claim 10 is to further define the ring previously defined in claim 2. However, as originally submitted, claim 10 erroneous refers to claim 3 for antecedent basis. Applicants have amended claim 10 to properly refer to claim 2 for antecedent basis to correct the typographical error. Therefore, applicants submit that this amendment is not a "substantial amendment related to patentability" within the meaning of Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F. 3d 558, 56 USPQ 2d 1865 (Fed. Cir. 2000), but instead relates merely to a matter of form.

V. The Double Patenting Rejection

Claims 1-24 were rejected under the judicially-created doctrine of obvious-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,036,702.

Applicants are submitting herewith a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c). The Terminal Disclaimer overcomes the double patenting rejection. The double patenting rejection should therefore be withdrawn.

A check in the amount of $55.00, in payment of the fee set forth in 37 C.F.R. § 1.20(d) for the Terminal Disclaimer, is enclosed.

VI. Applicants' Invention

As set forth in independent claim 1, applicants' invention is directed towards a connector for use in connecting the axial end portion of a tubular graft to the side wall of a patient's tubular body tissue conduit so that the lumen of the graft communicates with the lumen of the conduit through an aperture in the side wall of the conduit to permit body fluid flow between the lumens without leakage. The connector includes an annular structure having first and second axially adjacent substructures. The first substructure (a) is disposed substantially concentrically inside the axial end portion of the graft, (b) is circumferentially enlargeable to press the axial end portion of the graft radially outwardly toward the body tissue surrounding the aperture, and (c) is resiliently biased to circumferentially enlarge to at least some degree by itself. The second substructure includes a plurality of struts that

are configured to extend substantially radially outwardly to engage the body tissue surrounding the aperture and hold the axial end portion of the graft in body-fluid-tight engagement with the side wall of the conduit annularly around the aperture. Applicants' invention may be used, for example, to provide a bypass around an occlusion or obstruction in a patient's coronary artery.

VII. Applicants' Reply to the Prior Art Rejections

The Claim Rejections Under 35 U.S.C. § 102(b)

Claims 1-5 and 24 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lazarus. Claims 1-4, 6, 16, and 24 were rejected under U.S.C. § 102(b) as being anticipated by Dwyer. The Examiner's rejections are respectfully traversed.

Both Lazarus and Dwyer disclose systems for securing tubular grafts within a patient's body tissue conduit. The tubular grafts may, for example, be placed at the location of an aneurysm. In Lazarus, each end of the graft is attached to the inner wall of the vessel with expandable spring means 131. The spring means forces the end of the graft outwardly and engages the inner surfaces of the vessel. Hook-like elements 151 are provided on the spring means to penetrate the vessel wall and oppose migration of the graft (see column 17, line 24 to column 18, line 21 of Lazarus). In Dwyer, each end of the graft is

attached to the inner wall of the vessel with self-expanding anchors 14 having hooks 24. The hooks, similar to the hook-like elements of Lazarus, extend outward to dig into the vessel wall to prevent migration of the graft (see column 9, lines 52-55 of Dwyer).

Neither Lazarus nor Dwyer discloses a connector for connecting an axial end portion of a graft to the side wall of a patient's tubular body conduit as defined in claim 1. Furthermore, neither Lazarus nor Dwyer discloses a connector for connecting an axial end portion of a graft to the side wall of a patient's tubular body conduit so that the lumen of the graft communicates with the lumen of the conduit through an aperture in the side wall of the conduit to permit body fluid flow between the lumens as defined in claim 1.

The Examiner asserts that the hook-like elements 151 and hooks 24, of Lazarus and Dwyer, respectively, are the equivalent of the second substructure of applicants' invention. This is not so. As described above, hook-like elements 151 and hooks 24 are provided to prevent the axial migration of the graft within a vessel. In contrast, applicants' second substructure includes a plurality of struts configured to extend substantially radially outwardly to engage the body tissue surrounding an aperture in the side wall to hold the axial end portion of the graft in body-fluid-tight engagement with the side wall of the

conduit annularly around the aperture. Therefore, applicants struts are fundamentally different from the hook-like elements and hooks of Lazarus and Dwyer, respectively.

Accordingly, for at least these reasons, independent claim 1 and dependent claims 2-24 are allowable over Lazarus and Dwyer. Applicants, therefore, request that the rejections based on Lazarus and Dwyer be withdrawn.

The Claim Rejection Under 35 U.S.C. § 102(e)

Claims 1-24 were rejected under U.S.C. § 102(e) as being anticipated by Goldsteen. The Examiner's rejection is respectfully traversed.

Goldsteen discloses methods and apparatus for delivering and installing graft tubing between two sections of a patient's existing body organ tubing and at least partly outside of that existing body organ tubing. In one embodiment, Goldsteen discloses a serpentine ring that is connected to the distal end of the graft tubing. The serpentine ring can be expanded to increase the size of connection between the organ tubing and the graft tubing. For example, balloon 422' may be used to expand the serpentine ring. The serpentine ring includes barbs that may flare out in a trumpet bell shape inside the organ tubing to secure the graft tubing to the organ tubing's side wall.

The Examiner asserts that claims 1-24 are clearly anticipated by Goldsteen. Contrary to the Examiner's assertion, Goldsteen fails to disclose or suggest a first substructure 448 that is circumferentially enlargeable to press the axial portion of the graft radially outwardly toward body tissue surrounding an aperture, where the first substructure is resiliently biased to circumferentially enlarge to at least some degree by itself as defined in independent claim 1.

Accordingly, for at least this reason, independent claim 1 and dependent claims 2-24 are allowable over Goldsteen. Applicants, therefore, request that the rejection based on Goldsteen be withdrawn.

The Claim Rejection Under 35 U.S.C. § 103(a)

Claims 8 and 9 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lazarus or Dwyer in view of Weier. The Examiner's rejection is respectfully traversed.

Claims 8 and 9 depend from claim 1, and are therefore allowable because claim 1 is allowable in view of the foregoing. Accordingly, applicants request that the rejection be withdrawn.

VIII. Conclusion

In view of the foregoing, claims 1-24 are in condition for allowance. This application is therefore in condition for allowance. Reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,

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I Hereby Certify that this Correspondence is being Deposited with the U.S. Postal Service as First Class Mail in an Envelope Addressed to: COMMISSIONER FOR PATENTS P.O. Box 2327 ARLINGTON, VA. 22202 on

December 14, 2001
Lillian Garcia

Lillian Garcia
Signature of Person Signing

APPENDIX A

Version of the Specification Showing Changes Made

At page 1, line 2 to page 1, line 4 as follows:

This is a continuation of application No. 08/839,199 (now U.S. patent 6,036,702), filed April 23, 1997, which is hereby incorporated by reference herein in its entirety.

At page 3, line 7 to page 3, line 19 as follows:

In view of the foregoing, even less traumatic approaches have been developed for revascularizing a patient, as described in Goldsteen et al. U.S. patent [application No. 08/745,618, filed November 7, 1996, and] 5,976,178, hereby incorporated by reference herein in its entirety. With such approaches, a graft (e.g., of saphenous vein) can be delivered to an operative site in the patient through the patient's existing arteries and veins. The graft is typically inserted between two attachment sites in the patient's existing body organs (e.g., between a site along the patient's aorta and a site along the coronary artery downstream from a coronary artery occlusion).

APPENDIX B

Version of the Claims Showing Changes Made

2. (Amended) The connector defined in claim 1 wherein the [annular structure] first substructure comprises:

a ring having convolutions that repeatedly traverse a circumference of the annular structure, the ring being circumferentially enlargeable by straightening out the convolutions to some degree.

10. (Amended) The connector defined in claim [3] 2 wherein the ring is produced from a tube by removing interdigitated portions from the tube, alternating removed portions extending in from opposite ends of the tube.